## Listing of All Claims Including Current Amendments

1. (Previously presented) A method of formulating a topical insulin composition comprising:

preparing a non-liposome phosphatidylcholine and polyglycol multilamellar liquid crystal phosphatidylcholine non-polar carrier for topical administration; and mixing an insulin solution into said carrier to entrap said insulin within said carrier, wherein said insulin is stabilized at room temperature.

2. (Previously Presented) The method of claim 1, wherein preparing said <u>phosphatidylcholine and polyglycol multilamellar liquid crystal</u> carrier comprises:

combining a polyglycol having a molecular weight of 200 and polyglycol having a molecular weight of 400 to form a polyglycol mixture;

shaving said phosphatidylcholine into said polyglycol mixture to form a phosphatidylcholine solution; and

mixing said phosphatidylcholine solution until said phosphatidylcholine solution is clear.

- 3. (Original) The method of claim 2, wherein said phosphatidylcholine <del>component</del> is polyenylphosphatidylcholine-enriched phosphatidylcholine.
- 4. (Previously Presented) The method of claim 2, wherein said phosphatidylcholine solution comprises 45% w/w phosphatidylcholine, 50% w/w polyglycol having a molecular weight of 200, and 5% w/w polyglycol having a molecular weight of 400.
- 5. (Previously Presented) The method of claim 2, wherein preparing said <u>phosphatidylcholine</u> and <u>polyglycol multilamellar liquid crystal</u> carrier further comprises <u>:</u>

warming said phosphatidylcholine solution to 40°C and milling said warmed phosphatidylcholine solution;

combining siloxylated polyether and polydimethylsiloxane to form a fluid; adding said fluid to said warmed <u>phosphatidylcholine</u> solution <del>carrier</del> and milling until said <u>phosphatidylcholine</u> solution is clear;

adding methyl paraben to said solution and milling until said methyl paraben dissolves in said solution;

warming water to 40°C and adding said warmed water slowly to said <u>phosphati-dylcholine</u> solution; and

ceasing milling of said <u>phosphatidylcholine</u> solution and sweeping said <u>phosphatidylcholine</u> solution to cool to room temperature.

6. (Previously Presented) The method of claim 5, wherein said <u>phosphatidylcholine</u> and polyglycol multilamellar liquid crystal carrier comprises 53.25% w/w phosphatidylcholine solution, 1.00% w/w siloxylated polyether, 1.00% w/w polydimethylsiloxane, 0.75% w/w methyl paraben, and 44.00% w/w water.

## 7. Cancelled

- 8. (Previously Presented) The method of claim 6, wherein said wherein said siloxylated polyether is dimethyl, methyl(propylpolyethylene oxide propylene oxide, acetate) siloxane.
- 9. Cancelled
- Cancelled
- 11. (Original) The method of claim 1, wherein said insulin solution is human recombinant insulin prepared in 0.01 N HCI.

- 12. (Cancelled)
- 13. (Original) The method of claim 1, said insulin solution is mixed into said carrier at room temperature for at least one hour.
- 14. (Original) The method of claim 1, said insulin solution is mixed into said carrier to obtain said insulin composition having a concentration of 20 mg/ml.
- 15 (Cancelled)
- 16. (Cancelled)
- 17. (New) A method of formulating a topical transdermal polypeptide composition comprising:

preparing a phosphatidylcholine and polyglycol multilamellar liquid crystal carrier for topical administration to skin; and mixing a polypeptide solution into said carrier to entrap the polypeptide solution within the carrier, wherein the polypeptide solution is stabilized at room temperature and the composition delivers the polypeptide by transdermal delivery upon application of the composition to skin.

18. (New) The method of claim 17, wherein preparing said phosphatidylcholine and polyglycol multilamellar liquid crystal carrier comprises:

providing a polyglycol;

shaving phosphatidylcholine into said polyglycol to form a phosphatidylcholine solution; and

mixing said phosphatidylcholine solution until said phosphatidylcholine solution is clear.

19. (New) The method of claim 18, wherein preparing said phosphatidylcholine and polyglycol multilamellar liquid crystal carrier further comprises:

warming said phosphatidylcholine solution to 40°C and milling said warmed solution;

combining siloxylated polyether and polydimethylsiloxane to form a fluid; adding said fluid to said warmed solution carrier and milling until said solution is clear;

adding methyl paraben to said solution and milling until said methyl paraben dissolves in said solution;

warming water to 40°C and adding said warmed water slowly to said solution; and

ceasing milling of said solution and sweeping said solution to cool to room temperature.

- 20. (New) The method of claim 19, wherein said polypeptide is selected from the group consisting of oxytocin, vasopressin, insulin, somatotropin, calcitonin, chorionic gonadotropin, menotropins, follitropins, somatostatins, progestins, and combinations of any of these.
- 21. (New) The method of claim 20, wherein said polypeptide solution is vasopressin solution.
- 22. (New) The method of claim 18, wherein the phosphatidylcholine is polyenylphosphatidylcholine-enriched phosphatidylcholine.
- 23. (New) The method of claim 17, wherein preparing said phosphatidylcholine and polyglycol multilamellar liquid crystal carrier comprises:

combining a polyglycol having a molecular weight of 200 and polyglycol having a molecular weight of 400 to form a polyglycol mixture;

shaving phosphatidylcholine into said polyglycol mixture to form a phosphatidylcholine solution; and

mixing said phosphatidylcholine solution until said phosphatidylcholine solution is clear.

24. (New) The method of claim 23, wherein preparing said phosphatidylcholine and polyglycol multilamellar liquid crystal carrier further comprises

warming said phosphatidylcholine solution to 40°C and milling said warmed solution;

combining siloxylated polyether and polydimethylsiloxane to form a fluid; adding said fluid to said warmed solution carrier and milling until said solution is clear;

adding methyl paraben to said solution and milling until said methyl paraben dissolves in said solution;

warming water to 40°C and adding said warmed water slowly to said solution; and

ceasing milling of said solution and sweeping said solution to cool to room temperature.

- 25. (New) The method of claim 24, wherein said phosphatidylcholine and polyglycol multilamellar liquid crystal carrier comprises 45% w/w phosphatidylcholine, 50% w/w polyglycol having a molecular weight of 200, and 5% w/w polyglycol having a molecular weight of 400.
- 26. (New) The method of claim 24, wherein the phosphatidylcholine is polyenylphosphatidylcholine-enriched phosphatidylcholine.
- 27. (New) The method of claim 24, wherein said polypeptide is selected from the group consisting of oxytocin, vasopressin, insulin, somatotropin, calcitonin, chorionic

Serial No. 10/750,390 Response to Decision on Appeal Page 7

gonadotropin, menotropins, follitropins, somatostatins, progestins, and combinations of any of these.

28. (New) The method of claim 26, wherein said polypeptide solution is vasopressin solution.